UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01- 12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Hon. Patti B. Saris** **Magistrate Judge Marianne B. Bowler** **LEAVE TO FILE GRANTED ON DECEMBER 17, 2009**

DEFENDANTS DEY, INC., DEY, L.P., AND DEY L.P., INC.'S SUR-REPLY MEMORANDUM OF LAW IN OPPOSITION TO THE UNITED STATES' MOTION TO CONSOLIDATE CASES FOR TRIAL

Faced with the prospect of trial, the DOJ has determined that consolidation of the Dey Action[1] and the Roxane Action best serves its own interests. By focusing only on its own affirmative case, the DOJ incorrectly claims that consolidation is warranted here. By promoting a legal causation theory that has already been rejected by this Court, it also attempts to tip the scales in favor of consolidation. Both of these arguments should be rejected, and this Court should decline to combine the two separate actions against Dey and Roxane.

I. CONSOLIDATION IS NOT WARRANTED BECAUSE IT WILL NOT SERVE THE INTERESTS OF JUDICIAL ECONOMY

Consolidation will cause demonstrable prejudice and juror confusion. The DOJ ignores the realities of a joint trial in which the DOJ would have to present its affirmative cases against both Dey and Roxane and in which Dey and Roxane would have to present their own defensive cases. The DOJ claims that "there is no reason to think that the evidence will vary significantly

[1] The capitalized and abbreviated terms used herein shall have the same definitions ascribed to them as in Dey's Opposition to the United States' Motion to Consolidate Cases for Trial, (Docket No. 6635) ("Opposition").

depending on the type of drug at issue", that the Dey Action and the Roxane Action involve "essentially identical evidence," and that consolidation is warranted "despite minor evidentiary differences." (Dkt. 6660 at 2-3, 5). This is simply not true. When this Court examined evidence in the MDL trial, it was not the general type of evidence the DOJ seems to want to offer but rather "company by company, but drug by drug, NDC by NDC, and even – and year by year" evidence. (MDL Transcript 7/3/07, at 22:15-21, previously attached as Ex. E to Dkt. 6635). This level of specificity, resulting in a large amount of Dey-specific and Roxane-specific evidence, will be needed here as well, and will only cause demonstrable confusion and prejudice were it presented in a joint trial. The risk of prejudice and confusion is not speculative, but is one that has already been found to exist by this Court and others that have dealt with AWP cases. (*See* Dey's Opposition, Dkt. 6635 at 7-8). Rather than address those courts, including this one, that have held that confusion and prejudice is a real concern in AWP cases, the DOJ relies on a series of primarily securities cases in arguing for consolidation. (Dkt. 6660 at 4-5). Such cases are inapposite here.

The DOJ insists that despite this Court's prior holdings, it does not plan to present "twelve different presentations relating to the marketing history of every drug" to a jury. (Dkt. 6660 at 3). Regardless of how the DOJ chooses to present its affirmative case, following the rubric established by this Court, it will be necessary for Dey and for Roxane to present unique drug and NDC level evidence in order to present their sides of the case. For example, the examination of Dey's albuterol at trial will involve, at a minimum, presentation of the following evidence: (1) Dey's pricing of albuterol products; (2) Dey's marketing of these products; (3) the price at which the DOJ contends should have been the ingredient cost of albuterol; (4) Medicare arrays from four DMERCs from 1992 to 2003; (5) pricing of albuterol in some 47 states under

Medicaid from 1992 to the present; (6) the Government's knowledge about the price of albuterol, including but not limited to the setting and removal of FULs for albuterol, revised DOJ AWPs for Dey's albuterol, the Congressional refusal to allow CMS to use inherent reasonableness authority to decrease the ingredient cost of albuterol, the numerous OIG reports regarding albuterol, the Dey invoices and other prices the Government had for Dey's albuterol, the cost of dispensing albuterol, access to albuterol within the Medicaid and Medicare programs, state MACs for albuterol, and other witness testimony, including expert witness testimony, regarding albuterol. This presentation will have nothing to do with Roxane or Roxane's drugs. Yet, in a consolidated trial, the jury will need to hear all of this information as well as similar information for the 12 other drugs at issue in the Dey and Roxane trials. Even the presentation of evidence on ipratropium will not be streamlined, as evidence of Roxane's entry as the first generic following the brand and its price reporting will be substantially different from Dey's subsequent introduction of its BAC-free ipratropium products and its marketing, price reporting, and ultimate price erosion. The other differences set forth in Dey's opposition also weigh in favor of separate trials. (Dey's Opposition, Dkt. 6635 at 2-6). This type of necessary evidence will add months to a lengthy trial and will require a jury to separate evidence while the DOJ attempts to conflate the two companies and their numerous drugs and NDCs.

Nor can juror confusion and prejudice be remedied by "presenting the evidence against each defendant sequentially, and giving cautionary jury instructions" as suggested by the DOJ. (Dkt. 6660 at 3). The breadth of evidence that will be necessary to support the DOJ's affirmative cases against Dey and Roxane as well as Dey and Roxane's defensive presentations is such that any possible jury instructions would be as complicated as the trial itself. *See, e.g., Walker v. H. Councill Trenholm State Tech. Coll.*, No. 2:06 cv 49-ID, 2007 WL 1140423, at *4 (M.D. Ala.

Apr. 17, 2007) (court disagrees that preventive measures, such as cautionary jury instructions, can sufficiently alleviate the potential of jury confusion or prejudice, and denies consolidation). Therefore, this Court should deny the DOJ's motion to consolidate.

II. CONSOLIDATION IS NOT WARRANTED BECAUSE OF THE DOJ'S JOINT IMPACT THEORY

In False Claims Act cases, the pertinent question is whether Dey individually caused injury. The DOJ's "joint impact" theory should not form the basis of consolidation.[2] The DOJ argues that its theory necessitates a consolidated trial. (Dkt. 6660 at 5). However, as previously recognized by this Court, "[u]se of a joint and several liability theory does not require that all tortfeasors are joined in the action." *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d 20, 100 at n. 79 (D. Mass. 2007). The DOJ's unproven legal theory is no cause for consolidation, especially because this Court has acknowledged that "I struggled with [this joint issue in the MDL class action suit], and there were no good cases on this." October 20, 2009 Hearing Tr. at 27:21-22.[3] In the MDL class action, this Court firmly rejected the DOJ's theory in Track 1, in which it held: "[g]iven that there are no claims or evidence of conspiracy or joint enterprise, the pertinent legal question is whether [a defendant] can be said to have *individually* caused the plaintiffs' injuries." *In re Pharm Indus. Avg. Wholesale Price Litig*., 491 F. Supp. 2d at 99 (emphasis added).

Rather than weighing in favor of consolidation, the DOJ's joint theory weighs against it. Consolidation will prejudice Dey and Roxane precisely because of the DOJ's joint Medicare theory. The DOJ admits that "after the third quarter of 2001, we can change the AWPs of Dey

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2 Dey does not intend to address in this sur-reply all of the legal deficiencies of the DOJ's "combined impact" theory of liability, and reserves its right to challenge further the DOJ's untenable theory at a later date.

3 This is because another competitor entered the market at a markedly higher AWP. The DOJ chose not to sue that competitor, presumably accepting that the high AWP was a "true" price in contrast to what it claims to be the case for Dey and Roxane.

down to a penny, and it doesn't change the outcome, the median calculation." October 20, 2009 Hearing Tr. at 25:2-4. By trying Dey and Roxane together because they have both been sued, despite never having alleged any claims of conspiracy or joint action between the two manufacturers, the DOJ attempts to create inferences where there is no evidence. Under the DOJ's theory, the DOJ's trial strategy and determination of which manufacturers to sue, rather than Dey's actions, assigns greater damages to Dey, despite the fact that the DOJ concedes Dey has not caused all of the DOJ's claimed damages. This Court should not allow the DOJ to create liability where there is none through the use of a consolidated trial.

III. THE DOJ'S PROPOSED "MEDICARE" TRIAL WILL NEITHER SAVE TIME NOR PREVENT CONFUSION

The DOJ's proposal to hold a consolidated trial in two phases before a single jury with the Medicare portion followed by the Medicaid portion will not reduce any confusion or prejudice, and will only lengthen and complicate trial. Were the proposal followed, the DOJ would presumably present elements of its causes of action as to the drugs at issue in Medicare but not Medicaid, as it admits that "Medicare case involves substantially fewer drugs" (Dkt. 6660 at 9). Then, for the Medicaid portion of the trial, the Government would present the same arguments as to its case-in-chief as to the remaining drugs at issue in its Medicaid case. Nor will separating Medicare from Medicaid save time or duplication of witnesses because there is only one AWP and AMP per drug, and therefore CMS' knowledge regarding AWP and AMP is CMS' knowledge for both Medicaid and Medicare, regardless of the program from which it was obtained. In Dey's case, there is also a reported WAC. Therefore, the testimony of CMS and OIG witnesses would need to be presented in both the Medicare and Medicaid portions of the trial, or, at a minimum, all of the evidence of government knowledge would need to be called twice and presented at the Medicare portion of the trial, which is clearly undesirable, and even

repeat or expand testimony for some drugs not at issue in Medicare. This is not a practical approach and should be rejected by this Court in favor of separate trials for Dey and for Roxane. The Dey trial is confined to three inhalation drugs which provide a clear focus for trial and would only require the introduction of evidence of Government action in regulating these drugs once. Dey's story, as a niche marketer, is unique and can be clearly presented to a jury by both sides. Trial will be much more streamlined, and accordingly shorter, with less likelihood of jury exhaustion or confusion. Under all these circumstances, and for the reasons stated in Dey's opposing brief, Roxane's opposing brief, and Roxane's sur-reply, this Court should deny the DOJ's motion to consolidate.

Dated: December 17, 2009

Respectfully Submitted,

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By: /s/ Sarah L. Reid

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on December 17, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid